DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 2004P–0141]

Determination That 7.5% and 8.4% Sodium Bicarbonate Injection in Polyethylene Terephthalate Abboject Vials Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that 7.5% and 8.4% sodium bicarbonate injection in polyethylene terephthalate (PET) Abboject vials were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for 7.5% and 8.4% sodium bicarbonate injection.

FOR FURTHER INFORMATION CONTACT: Nicole Mueller, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an abbreviated new drug application (ANDA) procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat

the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162) (21 CFR 314.162)).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

The drug products 7.5% and 8.4% sodium bicarbonate injection in PET Abboject vials are the subject of approved NDA 19–443 held by Abbott Laboratories. The drug products 7.5% and 8.4% sodium bicarbonate injection in PET Abboject vials are indicated for the treatment of metabolic acidosis, certain drug overdosage, and severe diarrhea. The holder of the application for 7.5% and 8.4% sodium bicarbonate injection in PET Abboject vials requested a voluntary withdrawal and the marketing of the drug products was discontinued (61 FR 40649, August 5, 1996). In a citizen petition dated March 18, 2004 (Docket No. 2004P–0141), submitted under 21 CFR 10.30 and 314.122,

Abbott Laboratories requested that the agency determine whether 7.5% and 8.4% sodium bicarbonate injection in PET Abboject vials were withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Abbott Laboratories' 7.5% and 8.4% sodium bicarbonate injection in PET Abboject vials were not withdrawn from sale for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse event reports and has found no information that would indicate that these products were withdrawn for reasons of safety or effectiveness.

For the reasons outlined, FDA determines that Abbott Laboratories' 7.5% and 8.4% sodium bicarbonate injection in PET Abboject vials were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list 7.5% and 8.4% sodium bicarbonate injection in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to 7.5% and 8.4% sodium bicarbonate injection may be approved by the agency.

Dated: 11/18/04

November 18, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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